UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD, et al.,

Plaintiffs,

v.

HANDA PHARMACEUTICALS, LLC, et al.,

Defendant.

Case No. C-11-00840 JCS

ORDER RE SUMMARY JUDGMENT MOTIONS [Docket Nos. 188, 192 (redacted publicly filed versions); 215, 230 (sealed versions)]

PUBLIC VERSION

~~FILED UNDER SEAL~~

[REDACTED VERSION]

SEALED DKT NO.

United States District Court
Northern District of California

I. INTRODUCTION

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (hereinafter, referred to collectively as "Takeda") initiated this action under 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, in response to Abbreviated New Drug Application ("ANDA") No. 202-294, filed with the Food and Drug Administration ("FDA") by Defendant Handa Pharmaceuticals, Inc. ("Handa"), seeking approval to market dexlansoprazole delayed release capsules as a generic version of Takeda's drug DEXILANT (dexlansoprazole). Handa and Par Pharmaceutical, Inc. ("Par") entered into an exclusive acquisition and license agreement concerning ANDA No. 202-294, and Par is now the owner of that ANDA.[1] Joint Statement of Undisputed Facts for Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("JSUF (Takeda Motion)") ¶¶ 5-6.

Takeda asserts that the ANDA products infringe the following patents (hereinafter, "Asserted Patents"): 1) U.S. Patent No. 6,462,058 ("the '058 Patent"); 2) U.S. Patent No.

[1] The Court refers to Handa and Par collectively as "Handa."

6,664,276 ("the '276 Patent"); 3) U.S. Patent No. 6,939,971 ("the '971 Patent"); 4) U.S. Patent No. 7,737,282 ("the '282 Patent"); 5) U.S. Patent No. 7,285,668 ("the '668 Patent") and 6) U.S. Patent No. 7,790,755 ("the '755 Patent"). Handa, in turn, asserts counterclaims seeking declaratory judgment of non-infringement and invalidity as to all of the Asserted Patents.

Presently before the Court are the parties' cross-motions for summary judgment. Takeda has filed a motion seeking summary judgment of infringement of the '282 Patent based on what it contends is undisputed evidence that the dexlansoprazole drug product in Handa's ANDA contains every element of claims 1 and 2 of the '282 Patent. *See* Docket No. 230 (Motion for Summary Judgment of Infringement of the '282 Patent ("Takeda SJ Motion (Handa)"). Handa brings a motion for partial summary judgment that: 1) its ANDA product does not infringe the '755 Patent because both Takeda's [redacted]; 2) its ANDA product does not infringe the '276 Patent because Takeda has not produced any evidence [redacted]; and 3) claims 1 and 2 of the '282 Patent are invalid because they are anticipated by the Larsson[2] and Barberich[3]

[2] "Larsson" refers to WO 96/02535 ("Larsson I") and U.S. Patent No. 5,948,789 ("Larsson II"). The parties agree that there is no material difference between the disclosures of Larsson I and Larsson II. Joint Statement of Undisputed Facts in Support of Defendants Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.'s Motion for Partial Summary Judgment ("JSUF (Handa Motion)") ¶ 23.

[3] "Barberich" refers to WO 99/38513 ("Barberich I") and U.S. Patent App. No. 2003/0008903 ("Barberich II"). The parties agree that there is no material difference between the disclosures of Barberich I and Barberich II. JSUF (Handa Motion) ¶ 24.

prior art references. *See* Docket No. 215 (Defendants Handa Pharmaceuticals, LLC's and Par Pharmaceutical, Inc.'s Motion for Partial Summary Judgment ("Handa SJ Motion")).[4]

Hearings on the motions were held on February 8, 2013 and February 22, 2013. For the reasons set forth below, Takeda's summary judgment motion is GRANTED. Handa's summary judgment motion is GRANTED in part and DENIED in part.[5]

II. BACKGROUND

A. The Accused Product

In its ANDA, Handa seeks FDA approval to market dexlansoprazole delayed-release capsules [redacted] It is also undisputed that: 1) the ANDA product is a pharmaceutical composition that contains at least one pharmaceutically acceptable excipient; [redacted]

According to Handa, [redacted]

[4] Handa also joins in TWi Pharmaceuticals, Inc.'s Motion for Summary Judgment in related Case No. C-11-1609 JCS as to TWi's request for summary judgment on the grounds that: 1) the '755 Patent is invalid as indefinite under *Honeywell* if the Court adopts Takeda's test for "begins to release"; and 2) claims 1 and 2 of the '282 Patent are invalid for lack of the required written description. *See* Docket No. 248. The Court's rulings on those issues are set forth in a separate order, filed in the related case, and are adopted in this case.

[5] The parties have consented to the jurisdiction of a United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

[redacted]

B. Asserted Claims of the '282 Patent

Takeda alleges that Handa's ANDA product infringes claims 1 and 2 of the '282 Patent. Claim 1 of the '282 Patent claims an "amorphous compound of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole or a salt thereof." JSUF (Takeda Motion) ¶ 1. The parties agree that the term "(R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1 H-benzimidazole" in the '282 Patent refers to dexlansoprazole. *Id.* ¶ 4. Claim 2 of the '282 patent, which depends from claim 1, requires a "pharmaceutical composition comprising the amorphous compound according to claim 1 and a pharmaceutically acceptable excipient, carrier or diluent." *Id.* ¶ 2. The Court has construed the term "amorphous compound" in claims 1 and 2 of the '282 Patent to mean "a non-crystalline solid that lacks the long-range order characteristic of a crystal." *Id.* ¶ 3; Claim Construction Order at 71.

C. Asserted Claims of the '755 Patent

Takeda alleges that Handa's ANDA product infringes claims 2, 4 and 6 of the '755 Patent, each of which depends from claim 1. JSUF (Handa Motion) ¶ 2. Claim 1 describes a capsule comprising two compositions, one of which is "soluble in the pH range of 6.0 to 7.5" ("composition (i)") and another in which the drug is "released in the pH range of no less than 5.0 to no more than 6.0" ("composition (ii)"). At the claim construction stage of the case, the Court was asked to construe the claim term specifying the range for composition (ii) (hereinafter, the "release term"). The primary dispute focused on whether the specified pH range refers to the threshold level at which release of the active ingredient begins, as Takeda asserted, or rather,

represents the *only* pH values at which release or dissolution occurs. The Court adopted Takeda's proposed construction, construing the claim term "released in the pH range of no less than 5.0 to no more than 6.0" to mean that the dexlansoprazole "begins to be released from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0." Claim Construction Order at 70. In response to the argument that the claim term is indefinite because a person skilled in the art would not know what percentage of the drug needs to be released to satisfy the "begins to be released" requirement, the Court noted that "the phrase 'begins to release' is not a claim term but merely a proposed construction intended to convey the idea that the pH values in the term represent a threshold." *Id.* at 67. The Court went on to find that the question of what amount of drug release satisfies this requirement does not render the claim term insolubly ambiguous to a person of ordinary skill in the art. *Id.*

D. Asserted Claims of the '276 Patent

Takeda alleges that the ANDA Product infringes claims 2 and 3 of the '276 Patent. JSUF (Handa Motion) ¶ 8. Claims 2 and 3 recite:

> 2. A crystalline compound of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1 H-benzimidazole.
>
> 3. A pharmaceutical composition comprising:
>
> a crystalline compound of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole or a salt thereof; and
>
> a pharmaceutically acceptable excipient, carrier or diluent.

The Court construed the term "crystalline compound" to mean "regularly repeating pattern of molecules with long range order extending in three dimensions." Claim Construction Order at 70.

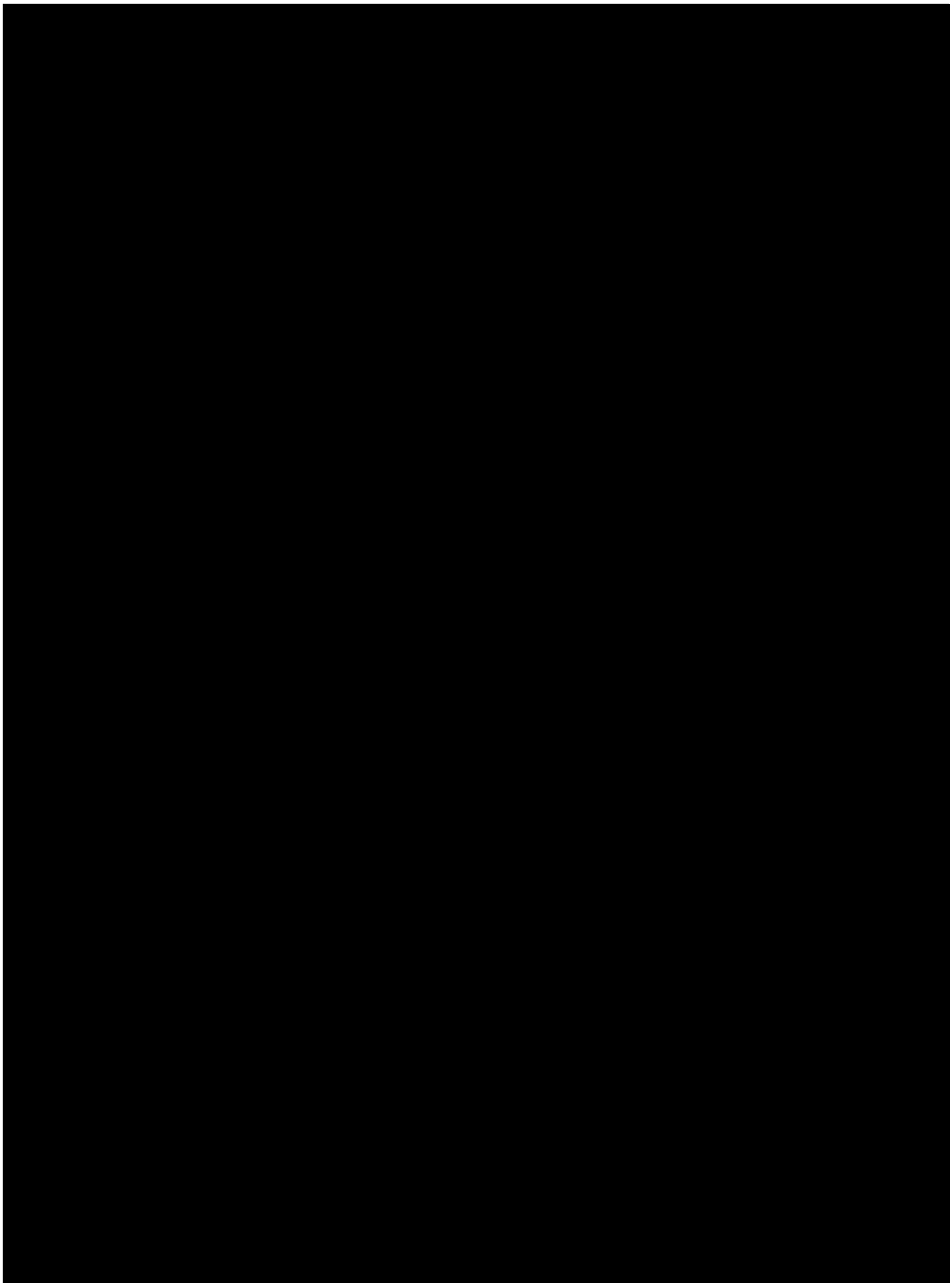
E. The Parties' Contentions

1. Infringement of the '282 Patent

a. Takeda's Motion

Takeda contends that it is entitled to summary judgment of infringement of claims 1 and 2 the '282 Patent, both of which require an amorphous compound of dexlansoprazole, on the basis

[redacted]



[redacted]

Takeda also cites the following statements made by Handa in this litigation: [redacted]

b. Handa's Opposition

In its Opposition, Handa argues that Takeda is not entitled to summary judgment of infringement of the '282 Patent because: 1) it is Takeda's burden to establish infringement and Takeda [redacted] Defendants Handa Pharmaceuticals, LLC's and Par Pharmaceutical, Inc.'s Opposition to Motion for Summary Judgment of Infringement of the '282 Patent ("Handa Opposition") at 4; 2) [redacted]

[redacted] 4) there is no subject matter jurisdiction over Takeda's '282 Patent infringement claims under 35 U.S.C. § 271(e)(2) because Takeda has not listed the '282 Patent in the "Orange Book." *Id.* at 9-12 (citing *Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958, at *6 (D.N.J. Dec. 20, 2007); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925, 936 (N.D.Ill.,1995)).

c. Takeda's Reply

In its Reply brief, Takeda again points to statements by Handa [redacted] Reply in Support of Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("Takeda Reply") at 1-3. In addition to the statements cited in Takeda's opening brief, Takeda cites statements by Handa in its own motion for summary judgment in which it states that its ANDA product [redacted] Reply at 1 (quoting Handa SJ Motion at p. v). Takeda also cites the Handa SJ Motion at 1 ("[T]he ANDA Product lacks a limitation common to each of the asserted claims of the '276 Patent, that is, a [redacted]

Takeda argues that if Handa's ANDA [redacted] Reply at 5. Takeda points to the Court's claim construction, which construes "amorphous compound" as solid and non-crystalline. *Id.* As it is undisputed that the [redacted] Takeda asserts. *Id.* at 5-6. Further, Takeda argues, because a solid must be either

crystalline or amorphous, Handa's assertions that [redacted] *Id.* at 6.

Takeda rejects Handa's argument that it is required to provide test results showing that the [redacted] *Id.* at 7 (citing *Martek Biosciences Corp. v. Nutrovina, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009)). Takeda notes that it [redacted] addressed in the briefing on Handa's request for summary judgment of noninfringement of the '276 Patent, [redacted] *Id.* at 8.

Takeda further contends that having made a showing that Handa's ANDA product [redacted] the burden shifted to Handa to produce specific evidence to show that a genuine dispute exists and that Handa, [redacted] has not met that burden. *Id.* at 9. Takeda rejects Handa's reliance on the deposition testimony of Dr. Myerson that [redacted] arguing that this testimony was taken out of context. *Id.* Takeda argues that Dr. Myerson merely testified that he cannot say [redacted] *Id.* at 11.

Takeda rejects Handa's assertion that the Court lacks subject matter jurisdiction under § 271(e)(2) because the '282 Patent is not listed in the Orange Book and Handa has not included a Paragraph IV certification as to the '282 Patent in its ANDA. *Id.* According to Takeda, Supreme Court and Federal Circuit authority establish that it is the submission of an ANDA, not a Paragraph IV certification, that gives rise to jurisdiction in the district courts for an act of infringement under § 271(e)(2). *Id.* at 11-12 (citing *Curaco Pharmaceutical Labs., Ltd. v. Novo*

Nordisk A/S, 132 S. Ct. 1670, 1680 n. 5 (2012); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1376-77 (Fed. Cir. 2012); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1343-44 (Fed. Cir. 2004); *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1372-73 (Fed. Cir. 2006)). Takeda cites district court decisions that it contends have reached the same conclusion. *Id.* at 20-21 (citing *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009); *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009). Further, Takeda asserts, the decision cited by Handa, *Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958, at *6 (D.N.J. Dec. 20, 2007), "stands alone against the great weigh of authority . . . in holding that a suit pursuant to § 271(e)(2) may not be brought if the asserted patent is not listed in the Orange Book." *Id.* at 13.

Finally, Takeda argues that Handa has misconstrued its complaint and ignored the plain language of Count VII in arguing that in its Second Amended Complaint Takeda did not assert infringement under § 271(a) based on Handa's use of amorphous dexlansoprazole in the manufacture of its ANDA product. Reply at 13-14. In particular, it points to the complaint's allegations that:

> 61. Defendants' commercial **manufacture**, use, sale, or offer for sale within the United States or importation into the United States **of the Proposed Capsules** will constitute infringement of the '058, '276, '971, '282, '668, and '755 Patents
>
> 62. Defendants' infringing commercial **manufacture**, use, sale, or offer for sale within the United States or importation into the United States **of the Proposed Capsules** complained of herein will begin following FDA approval of ANDA No. 202-294.
>
> 63. . . .Plaintiffs thus are entitled to a declaration that the **making**, using, sale, offer for sale, and importation into the United States **of the Proposed Capsules** according to ANDA No. 202-294 infringe one or more claims of the Asserted Patents.

Id. (quoting Second Amended Complaint, ¶¶ 61-63 (emphasis added in Reply brief)). This language, Takeda contends, makes clear that its claim encompasses not only infringement based

on the finished ANDA product but also infringement arising from the use of a patented invention in the manufacture of Handa's ANDA product. *Id.*

2. Validity of the '282 Patent

a. Handa's Motion

Handa contends that claims 1 and 2 of the '282 Patent are anticipated by both Larsson and Barberich and therefore, are invalid. Handa SJ Motion at 19-24. With respect to Larsson, Handa argues that there is no genuine dispute of material fact that this prior art discloses an "amorphous compound" of dexlansoprazole or a "salt thereof," which is the only requirement of claim 1 of the '282 Patent. *Id.* at 19. Handa notes that the Court has construed the term "amorphous compound" as "a non-crystalline solid that lacks the long-range order characteristic of a crystal." *Id.* It further points out that the parties are in agreement that Example 22 of Larsson discusses a process involving placing lansoprazole in a solvent, precipitating the lansoprazole, and evaporating off the solvent, and that Larsson reported obtaining an oil of dexlansoprazole after this process was performed "a couple of times." *Id.* (citing Rogers Decl., Ex. 6 (Expert Report of Robin D. Rogers, Ph.D. Regarding Invalidity of U.S. Patent No. 7,737,282 ("Rogers Report") at ¶¶ 68, 73; Jansen Decl., Ex. 11 (Expert Report of Jerry L. Atwood, Ph.D., in Response to the Expert Reports of Robin D. Rogers, Ph.D., and Edmund J. Elder, Jr., Ph.D., R.Ph., Regarding the Validity of the '282 Patent ("Atwood Report")) at ¶¶ 66, 67; *id.*, Ex. 6 (Oct. 16, 2012, Atwood Dep. Tr.) at 21:1-22:23). Thus, the only remaining question is whether the undisputed facts show that Larsson discloses a solid, as is required under the Court's claim construction. *Id.* Handa contends that it does because Larsson *inherently* discloses a solid amorphous compound of dexlansoprazole. *Id.*

To establish inherent disclosure of an amorphous compound of dexlansoprazole, Handa cites deposition testimony of Takeda's experts, Drs. Myerson and Atwood, as well as testimony by its own experts, Drs. Rogers and Elders, that it contends supports the conclusion that if one were to repeat the process described in Example 22 more than a couple of times, one would eventually obtain a solid. *Id.* at 19-20 (citing Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 32:11-33:20; 35:3-21; 37:21-38:3; 42:17-43:12; *id.*, Ex. 14 (Oct. 25, 2012 Myerson Dep. Tr.) at

134:21-135:19; *id.*, Ex. 7 (Oct. 17, 2012 Atwood Dep. Tr.) at 233:14-234:12; *id.*, Ex. 3 (Oct. 12, 2012 Elder Dep. Tr.) at 58:1-6; 69:3-22). Handa also cites the results obtained by researchers at the University of Wisconsin ("UW") who, working under the direction of Dr. Elder (one of Handa's experts), allegedly obtained a solid by replicating the synthesis described in Example 22 of Larsson. *Id.* at 20 (quoting Declaration of Edmund J. Elder, Jr., Ph.D., R.Ph., In Support of Defendants' Motion for Partial Summary Judgment ("Elder Decl."), Ex. 4 (Final Report for Custom Synthesis (hereinafter, "UW Report")) at 3, 10 ("[t]he final enriched product of R-(+)-lansoprazole was isolated as a brown dry foam, which could be transferred to a vial via spatula. The dry foam crumbled into a powder when transferred."). According to Handa, Takeda's expert, Dr. Atwood, did not dispute that the UW researchers obtained an amorphous compound of dexlansoprazole, nor did he question the XRPD analysis conducted by them. *Id.* (citing Jansen Decl., Ex. 6 (Oct. 16, 2012 Atwood Dep. Tr.) at 215:19-216:2). Handa further notes that Dr. Atwood did not attempt to perform the process disclosed in Example 22 himself. *Id.* (citing Jansen Decl., Ex. 6 (Oct. 16, 2012 Atwood Dep. Tr.) at 204:15-205:4; 211:23-212:6). Therefore, Handa contends, Dr. Atwood's opinion that "Larsson was unable to obtain (R+)-lansoprazole as an amorphous solid" according to Example 22 and that it would be "unlikely that the ordinarily skilled person performing those steps in 1999 could have" done so is unfounded. *Id.* at 20-21 (citing Jansen Decl., Ex. 11 (Atwood Report) at ¶ 81).

Handa further asserts that claim 2 of the '282 Patent is anticipated by Larsson. *Id.* at 21. As noted above, claim 2 depends from claim 1 and recites the additional limitation that the amorphous compound must be part of a "pharmaceutical composition" comprising "a pharmaceutically acceptable excipient, carrier or diluent." According to Handa, "[a]lthough Dr. Atwood disputes Dr. Rogers' assertion that water, which is disclosed in Larsson, is a pharmaceutically acceptable diluent . . . , he does not challenge any other assertions regarding Larsson with respect to the 'pharmaceutical composition' limitation of claim 2 of the '282 Patent." *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 161; Jansen Decl., Ex. 11 (Atwood Report) at ¶ 93). Therefore, Handa contends, it is undisputed that Larsson discloses the use of an

amorphous compound of dexlansoprazole in a pharmaceutical composition. *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶¶ 158-160, 162-63).

According to Handa, the asserted claims of the '282 Patent are also anticipated by the Barberich prior art. First, Handa contends, it is undisputed that Barberich incorporates by reference the synthesis of dexlansoprazole disclosed in Larsson and therefore, that Barberich, like Larsson, inherently discloses an "amorphous compound" of dexlansoprazole. *Id.* at 22 (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 200; Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 79:12-25; 80:1-6; *id.*, Ex. 11 (Atwood Reports) at ¶ 70; *id.*, Ex. 7 (Oct. 17, 2012 Atwood Dep. Tr.) at 317:21-318:10). Second, Handa argues that Barberich *literally* discloses an "amorphous compound" of dexlansoprazole as it discloses "[c]ompressed tablets [that] may be prepared by compressing in a suitable machine the active ingredient in a freeflowing form such as a powder or granules." *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 200 (quoting Barberich I)). In addition, Handa's expert points to Examples 1 and 2 of Barberich, which he contends disclose solid oral dosage forms using dexlansoprazole. *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 201; Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 86:16-88:7).

Handa rejects the opinion of Dr. Atwood that the disclosure in Barberich is merely "prophetic" and that the Barberich inventors did not actually create an amorphous compound of dexlansoprazole. *Id.* at 22-23 (citing Jansen Decl., Ex. 7 (Atwood Dep.) at 318:11- 319:14; 321:4-21; *id.*, Ex. 11 (Atwood Report) at ¶¶ 71, 102). Arguing that Dr. Atwood's opinion was unfounded, Handa points to his testimony that he did not "know Barberich." *Id.* (citing Jansen Decl., Ex. 7 (Oct. 17, 2012 Atwood Dep. Tr.) at 319:15-16). As further evidence that Dr. Atwood's opinion is "baseless," Handa points to a statement in Takeda's interrogatory responses that it is "possible" that Barberich Examples 1 and 2 were only "paper experiments." *Id.* (citing Jansen Decl., Ex. 12 (Plaintiffs' Responses To Handa Pharmaceuticals LLC's First Set Of Interrogatories) at 6) ("as Examples 1 and 2 of Barberich are written in the present tense, it is possible that these Examples were paper examples and not actually performed"). Further, according to Handa, Dr. Atwood's position is based on an incorrect understanding of the law because even a "prophetic" disclosure is sufficient to establish anticipation. *Id.* at 23. In

particular, Handa contends that the law does not require actual creation or reduction to practice of prior art subject matter but only that an anticipatory reference "enable subject matter that falls within the scope of the claims at issue." *Id.* at 23 (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed. Cir. 2003); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)).

Handa argues that Barberich also anticipates claim 2 of the '282 Patent because it discloses using dexlansoprazole to treat patients and teaches pharmaceutical compositions containing dexlansoprazole. *Id.* at 23-24 (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 208; Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 82:7-14).

b. Takeda's Opposition

Takeda argues that the asserted claims of the '282 Patent are not anticipated by either Larsson or Barberich. Takeda's Opposition to Handa and Par's Motion for Partial Summary Judgment ("Takeda Opposition") at 15-19. With respect to Larsson, Takeda rejects Handa's contention that Larsson inherently discloses the synthesis of an "amorphous compound" of dexlansoprazole, arguing that the evidence does not show that Example 22 *necessarily* results in the synthesis of such a compound. *Id.* at 16. First, it argues that the testimony of the Handa experts – that had the inventors repeated the process in Example 22 they would have obtained an amorphous solid – is not sufficient because Larsson does not disclose that the oily form described in Example 22 may be evaporated to obtain a solid. *Id.* According to Takeda, even assuming these experts were correct, this testimony would represent only the common knowledge of the skilled artisan, which cannot be used to establish inherency. *Id.* (citing *Rockwell Int'l Corp. v. SDL, Inc.*, 103 F. Supp. 2d 1202, 1207 (N.D. Cal. 2000) (citing *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984))). Further, Takeda contends, this would not have been common knowledge as Example 22 suggests the opposite, namely, that repeating the procedure would result in an oil. *Id.* at 16-17.

Takeda also challenges Handa's reliance on the testimony of its experts, Drs. Myerson and Atwood. *Id.* at 17. With respect to Dr. Myerson, Takeda argues that his deposition testimony on anticipation is inadmissible hearsay and should be excluded because he is Takeda's expert on infringement, not validity, and therefore, Handa may use his deposition testimony only to

impeach his opinions on infringement. *Id.* (citing Fed. R. Civ. Proc. 32(a); 8A Fed. Prac. & Proc. Civ. § 2145 (3d Ed. 2012); *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 2005 WL 2296613, at *2 (D. Del. Sept. 20, 2005)). Further, it argues, Dr. Myerson's opinion does not establish anticipation as he merely testified that "[i]f you dried the oil, which is very hard to do, you should be able to eventually make it what you would consider an amorphous solid. But it might take a really long time." *Id.* (quoting Jansen Decl., Ex. 14 (Oct. 25, 2012 Myerson Dep. Tr.) at 134:21 - 135:19). This testimony, Takeda argues, is insufficient to establish anticipation and relates only to obviousness. *Id.* (citing *Structural Rubber Prods.*, 749 F.2d at 716; *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008)). Dr. Atwood's testimony also does not establish anticipation, Takeda argues. *Id.* Dr. Atwood only testified that "it is possible that the oil is going to set into a solid." *Id.* (citing Purles Opposition Decl., Ex. 11 (Oct. 17, 2012 Atwood Dep. Tr.) at 233:14-238:14). According to Takeda, this testimony does not meet the requirement for inherency that such a result is inevitable. *Id.* at 17-18.

Takeda also rejects Handa's reliance on the experiments by Dr. Elder and the UW researchers in which the process in Example 22 was repeated and allegedly resulted in the synthesis of a solid. *Id.* at 18. First, Takeda argues that the UW lab "did not obtain an amorphous solid of dexlansoprazole by evaporating an oil to dryness; rather, the UW lab obtained a solid immediately *before* the final evaporation step in Example 22, and never actually obtained an oil. *Id.* (citing Elder Decl., Ex. 4 (UW Report) at 8 (emphasis in Takeda brief)).[6] Second, Takeda

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[6] At the February 22, 2013 hearing, Takeda conceded that this opinion was not stated by any of its experts. Takeda pointed to the following passage in the UW Report in support of its assertion:

> After stirring for 16 h at room temperature, to the solution was added toluene (50 ml) and the resultant solution was extracted three times with aqueous ammonia (12%, 3x100 ml). The combined aqueous layers were neutralized by the addition of concentrated acetic acid (30 ml). Thereafter, the workup procedure employed extraction by ethyl acetate (3x100 ml), evaporation and by silica gel flash column chromatorgraphy . . . yielding 1.4 g of light brown solid (yield: 65%) title compound with enantiomeric excess (e.e.) of 56 % (chiral analysis). After treating the residue with acetonitrile there was obtained a precipitate that was removed by filtration. Evaporation of the filtrate afforded a foam product with enhanced optical purity. Performing this procedure 5 total times . . . afforded

argues that the UW research does not establish inherency because the only way the researchers could obtain a solid amorphous compound of dexlansoprazole was by departing from the plain language of the experimental protocol described in Example 22. *Id.* (citing Jansen Decl., Ex. 11 (Atwood Report) at ¶¶ 89-90). In particular, when the UW researchers applied "as strict of [an] interpretation of the Larsson procedure as possible," their first attempt resulted in a solid of racemic lansoprazole rather than dexlansoprazole. *Id.* (citing Elder Decl., Ex. 4 (UW Report) at 3-4). [7] Thus, in order to obtain the solid amorphous compound, Takeda contends, the UW researchers had to adjust the procedure by adding the oxidant (cumene hydroperoxide) drop-by-drop over a period of 30 minutes via syringe pump – which is a procedure that is not described anywhere in Example 22. *Id.* (citing Elder Decl., Ex. 4 (UW Report) at 4, 8; Jansen Decl., Ex. 11 (Atwood Report) at ¶¶ 83-84; Purles Opposition Decl., Ex. 12 (Oct. 12, 2012 Elder Dep. Tr.) at 42:6-43:22) (testifying that Example 22 does not describe adding cumene hydroperoxide). Because the researchers obtained the amorphous compound of dexlansoprazole in only one of two experiments and had to adjust the protocol in the second one to include steps that were not described in Example 22, Takeda asserts, this evidence does not establish inherency. *Id.* (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-1269 (Fed. Cir. 1991)).[8]

Takeda argues that Barberich "adds nothing to the analysis." *Id.* Takeda does not dispute that Barberich refers to solid pharmaceutical compositions of dexlansoprazole but contends that it does not disclose the synthesis of any solid form of dexlansoprazole; instead, it merely incorporates by reference prior art such as Larsson. *Id.* at 18-19 (citing Jansen Decl., Ex. 11

> 0.53 g (24.5 % yield) of the desired compound as a brown foam with an optical purity of 97.8 % ee.

Elder Decl., Ex. 4 (UW Report) at 8.

[7] At the February 22, 2013 hearing, Handa conceded that on their first attempt, the UW researchers obtained a racemate rather than dexlansoprazole.

[8] At the February 22, 2012 hearing, Takeda cited a case that was not included in its brief, *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) in support of their argument that the UW research cannot be used to "fill in the gaps" for Larsson's inadequate disclosure. The Federal Circuit stated in *Scripps* that "a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations." 927 F.2d at 1576.

(Atwood Report) at ¶¶ 70-71, 100-106). Takeda cites the testimony of both Drs. Rogers and Dr. Genck (the expert of Impax Laboratories, Inc., a defendant in Related Case No. 11-01610 JCS) that Barberich does not add any teachings regarding the synthesis of dexlansoprazole to the teachings of Larsson. *Id.* at 19 (citing Purles Opposition Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 78:1-82:20; *id.*, Ex. 14 (Oct. 15, 2012 Genck Dep. Tr.) at 121:16-125:20). Because Barberich does not "enable one of skill in the art to reduce the disclosed invention to practice," Takeda argues, it does not anticipate the asserted claims of the '282 Patent. *Id.* (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003)).

c. Handa's Reply

In its Reply brief, Handa points out that Takeda did not address the question of whether Larsson or Barberich disclose the "pharmaceutical composition" limitation of claim 2 of the '282 Patent, therefore implicitly conceding that this limitation is disclosed in the prior art. Defendants Handa Pharmaceuticals, LLC's and Par Pharmaceuticals, Inc.'s Reply in Support of Motion for Partial Summary Judgment ("Handa Reply") at 12 n. 7. Thus, the only question as to anticipation is whether Larsson and Barberich anticipate on the basis of disclosure of a solid amorphous compound of dexlansoprazole.[9]

Handa argues that Takeda has applied the wrong legal standard to the extent it contends Larsson must expressly recognize that the oil described in Example 22 may be evaporated to obtain a solid. *Id.* at 13. The correct standard, Handa asserts, requires only that the "feature necessarily results from what was disclosed." *Id.* (citing *Schering*, 339 F.3d at 1377; *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999); *Atlas Powder Corp. v. IRECO Inc.*, 190 F.3d 1342, 1348-1349 (Fed. Cir. 1999)). According to Handa, all of the experts agree that repetition of Example 22 in Larsson would result in the synthesis of such a compound and this is sufficient to establish anticipation. *Id.* at 12-13. It is not sufficient, according to Handa, that it might be difficult or take a long time to obtain a solid amorphous

[9] Handa states in its brief that it does not concede that Larsson does not expressly disclose an amorphous solid of dexlansoprazole but that this issue is in dispute and therefore "does not form the basis for the present motion." Handa Reply at 12 n. 8. At oral argument, however, Handa conceded that Larsson does not expressly disclose an amorphous solid of dexlansoprazole.

compound of dexlansoprazole, as Dr. Myerson testified, as this is not the test for undue experimentation, Handa argues. *Id.* at 13-14 (citing *Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1370 (Fed. Cir. 1999); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998)). Handa also rejects Takeda's argument that Dr. Myerson's testimony on validity is inadmissible, arguing that Rule 56(c)(2) of the Federal Rules of Civil Procedure permits the citation of deposition testimony and Takeda has not demonstrated that Dr. Myerson's testimony could not be presented at trial in "a form that would be admissible." *Id.* at 14 n. 13.

Further, according to Handa, Dr. Atwood did not deny that repeating the process in Example 22 would result in the synthesis of a solid amorphous compound of dexlansoprazole, admitting that it was "possible" that this would result if the procedure in Example 22 were performed "two, three, four, five, six times." *Id.* at 14. Handa points out that Dr. Atwood himself made no attempt to replicate the process described in Example 22. *Id.* at 14. Because Takeda has introduced no evidence to contradict the experts' unanimous opinion that performing Example 22 will result in an amorphous solid, Handa argues, *Glaxo* and *Continental Can*, cited by Takeda, are not applicable here. *Id.* at 14 n. 13.

In a footnote, Handa also cites the conclusion of Dr. Elder and the UW researchers that repetition of Example 22 yields an amorphous solid of dexlansoprazole. Handa states that "[w]hile Takeda challenges that testing, it fails to raise any genuine dispute of material fact . . . and summary judgment may in any event be granted on the remaining facts that are not in dispute, identified herein." *Id.* Handa does not, however, address Takeda's specific arguments, based on the expert opinion of Dr. Atwood, that only one of the two experiments resulted in the creation of an amorphous compound of dexlansoprazole and that the second experiment required a change in the protocol that was not described in Example 22.

Finally, Handa argues that Takeda has not demonstrated a material issue of fact as to anticipation by Barberich. *Id.* at 15. Handa notes that Takeda does not dispute that Barberich describes "the active ingredient in a free-flowing form such as a powder or granule," and therefore, that Barberich expressly discloses an amorphous solid of dexlansoprazole. *Id.* (citing Takeda Opposition at 18-19). Handa contends that even if this disclosure is "prophetic," as Dr.

Atwood testified, it is sufficient to anticipate and further, that Takeda waived any argument to the contrary because it did not dispute that a "prophetic" disclosure can anticipate in its Opposition brief. *Id.* at 15 n. 14.

d. Supplemental Briefing

Following the motion hearings, the parties submitted supplemental briefs at the request of the Court addressing which party bears the burden of proving enablement when a patentee raises nonenablement to rebut anticipation based on prior art under 35 U.S.C. § 102. *See* Docket Nos. 256, 258.

3. Infringement of the '755 Patent

a. Handa's Motion

Handa seeks entry of summary judgment of non-infringement of the '755 Patent on the basis that it is undisputed that the [redacted] Handa rejects Dr. Charman's opinion that these data do not establish infringement because a person skilled in the art would understand that the "begins to be released" requirement is not met unless there is "rapid and significant" release of dexlansoprazole, that is, at least 10% release of the drug in less than two hours. *Id.* (citing Amiji Decl., Ex. 4, at ¶ 88-89). [10] According to Handa, Takeda's position amounts to an improper

[10] [redacted]

attempt to reargue the Court's construction of the release limitation and is contrary to: 1) the specification of the '755 Patent; 2) the applicants' arguments during prosecution of the '755 Patent; and 3) Takeda's arguments during claim construction in this action. *Id.* at 6.

Handa contends that "nothing in the claims or specification of the '755 Patent support[s] an argument that the dissolution measurement must be conducted at 120 minutes (two hours), or that there is no 'release' for the purpose of the pertinent claim term until more than 10% of the dexlansoprazole in the L-pellets has been released." *Id.* at 6-7. According to Handa, "[t]he only reference in the '755 Patent to an appropriate dissolution protocol refers to dissolution measurement after five to eight hours in solution." *Id.* at 7 (citing '755 Patent, col. 10, ll. 13-17 ("The rate of elution of active ingredient from the active ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8")).

Looking to the prosecution history of the '755 Patent, Handa cites remarks to the PTO by the applicants in which they relied on the declaration of one of the inventors, Dr. Takashi Kurasawa, describing the results of dissolution testing that he conducted over a 6-8 hour period. *Id.* (citing Jansen Decl., Ex. 8, at DEX0007130-31). According to Handa, the applicants "affirmatively presented the Kurasawa test methodology and results to distinguish the Beckert prior art reference that had been asserted by the Examiner" by relying on Kurasawa's release measurements at six hours. *Id.* Handa quotes the following statements of the applicants in support of this point:

> As shown in Fig. 1 of the attached Declaration of Mr. Takashi KURASAWA, who is one of the inventors of the present invention, Granule H in the Declaration, dissolves at pH 6.8 almost 100% in 6 hours and more than 30% in 4 hours. Further, in Fig. 1 of the Declaration of Mr. Kurasawa, composition (ii) of claim 41[now claim 1], i.e., Granule L-S, dissolves at pH 6.8 almost 100% at 2 hours. . . . further, the composition (i) of claim 41 dissolves at pH6.0-7.5, and dissolves completely at pH 6.8 at 6 hours . . . . The [Beckert] reference, however, discloses that not more than 20% of the active ingredient in pellet B is released at pH 6.8 after 6 hours.

Id. (quoting Jansen Decl., Ex. 8 at DEX0007130-31). Handa further points to Figure 1 in the Kurasawa affidavit, which it contends shows release of less than 5% of the dexlansoprazole at two hours, less than 10% at three hours and 30% at four hours. *Id.* at 8 (citing Jansen Decl., Ex. 8, at DEX0007124). In other words, Handa argues, the applicants relied on test results showing release of less than 5% of the dexlansoprazole after two hours; thus, the embodiment offered by the applicants to distinguish Beckert would not have fallen within the scope of the claims under Dr. Charman's approach. *Id.* Such a result, according to Handa, is disfavored. *Id.* at 8 (citing *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008)).

Handa also points to Takeda's arguments on claim construction, citing Takeda's reliance on the same dissolution data in the prosecution history in support of its position that the release term is not indefinite because a person of ordinary skill in the art could easily replicate the testing methodology described in the prosecution history. *Id.* (citing JSUF (Handa Motion), at ¶6).

Finally, [redacted]

b. Takeda's Opposition

Takeda does not dispute that the [redacted] It contends, however, [redacted] Takeda Opposition at 2-3. Takeda notes that the Court explicitly declined to specify at the claim construction stage of the case what type of testing would be required to determine whether the release term was satisfied, leaving this question to be addressed at trial through expert testimony. *Id.* at 4. This approach is consistent with Federal Circuit precedent, Takeda asserts, pointing to cases holding that courts need not eliminate all ambiguity in

construing claim terms but rather, should only define terms to the level of specificity that is warranted by the language of the claim and the evidence. *Id.* at 4-5 (citing *Acumed LLC v. Strkyer Corp.*, 483 F.3d 800 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351 (Fed. Cir. 1998); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341 (Fed. Cir. 2001); *Modine Mfg. Co. v. Int'l Trade Comm'n*, 75 F.3d 1545 (Fed. Cir. 1996)). According to Takeda, "where 'the claim language does not require a particular form of testing, this inquiry is not a claim construction question' but is 'review[ed] . . . as a question of fact.'" *Id.* at 5 (quoting *Union Carbide Chems. and Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366, 1377 (Fed. Cir. 2005), overruled on other grounds by *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009)).

Takeda argues further that there is a genuine dispute of material fact as to the testing criteria that should be used to decide whether Handa's ANDA product meets the release limitation and that substantial evidence supports Dr. Charman's approach. *Id.* Takeda points to the following evidence in support of Dr. Charman's approach:

- the monograph on dissolution testing in the United States Pharmacopeia ("USP"), which recognizes that for delayed-release dosage forms, a product passes a dissolution test if no individual dosage unit shows more than 10% dissolution in acid medium. *Id.* at 6 (citing Charman Decl., Ex. A.22[11] (2012 USP section on dissolution) at 301, Acceptance Table 3; Takahashi Decl., Ex. F (1995 USP section on dissolution) at 1796, Acceptance Table 2).
- the USP section on delayed release lansoprazole (which is an enantiomer of dexlansoprazole), which "permits dissolution of less than 10% in the acid stage in a two-stage experiment designed to simulate passage through an acidic stomach (in the first stage) followed by simulated intestinal dissolution (in the second stage)." *Id.* (citing Takahashi Decl., Ex. G (2009 USP section on lansoprazole delayed-release capsules) at

[11] Takeda has submitted separate expert reports by Dr. Charman for each of the three defendants in the related cases. Dr. Charman's report on Handa's accused product is designated as Exhibit A to his declaration and the exhibits attached to Dr. Charman's Handa report are designated as A.1 to A.23.

2753 (stating as to acid stage "[t]olerances" that "[n]ot more than 10% of the labeled amount of [lansoprazole] is dissolved in 60 minutes")).

[redacted]

- testimony of Handa's expert, Dr. Mansoor Amiji, that the typical transit time through the small intestine is 3.5 to 4.5 hours, with the pH level rising continuously through the length of the intestine. *Id.* (citing Purles Decl., Ex. 4 (Nov. 14, 2012 Amiji Dep. Tr.) at 127:7-129:24 & Ex. 18 (Dep. Ex. 105) at 5). Takeda asserts that in light of the fact that the '755 Patent envisions two distinct releases, one at the upper end of the small intestine and another at the lower end of the small intestine, this testimony offers further support for the time period suggested by Dr. Charman for measuring dissolution. *Id.* at 7-8 (citing '755 Patent, col. 1, ll. 53-57 ("After administered orally, the tablet, granule or fine granule migrates through gastrointestinal tract with [sic] releasing an active ingredient to stomach, duodenum, jejunum, ileum and colon sequentially").
- the FDA's Dissolution Methods Database entry for dexlansoprazole, recommending that in testing dexlansoprazole dissolution, sampling for the acid stage should be conducted at 120 minutes. *Id.* at 8 (citing Takahashi Decl., Ex. P (Dissolution Methods)).
- testimony by Impax's expert, Dr. Augsburger, that once the delayed release product reaches its target pH, the release should be "relatively rapid." *Id.* (citing Purles Decl., Ex. 10 (Nov. 16, 2012 Augsburger Dep. Tr.) at 116:6-18).

- the statement in the '755 Patent specification that "the usual enteric coat" dissolves "rapidly." *Id.* (citing '755 Patent, col. 6, l. 66 - col. 7, l. 12).
- Dr. Charman's deposition testimony that "any meaningful test for infringement must have an amount limitation to account for small amounts of dissolution that inevitably occur in any in vitro dissolution test of any significant duration," especially in light of manufacturing defects that commonly result in inappropriately coated or uncoated drug in the formulation. *Id.* (citing Purles Decl., Ex. 1 (Oct. 31, 2012 Charman Dep. Tr.) at 23:18-30:4, 180:20-181:8, 182:22-183:12, 254:20-260:22); *id.* Ex. 6 (Nov. 1, 2012 Charman Dep. Tr.) at 58:14-59:8).

Takeda argues that Handa's reliance on the '755 Patent specification and prosecution history, is misplaced. *Id.* at 9. As to Handa's reliance on col. 10, ll. 13-17 of the '755 Patent, stating that "[t]he rate of elution of active ingredient from the active ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8," Takeda contends that the specification makes clear that the threshold pH for this formulation was "6.75 or above." *Id.* (citing '755 Patent, col. 10, l.2). In other words, according to Takeda, "'rapid and significant' release for this particular embodiment would only be expected at a pH of 6.75 or higher." *Id.* Takeda reasons, "[t]hat release was relatively slow and minimal at pH 6.0, a pH level significantly below the target pH of this particular embodiment, is in no way inconsistent with Dr. Charman's opinion that the claimed formulation should show rapid and significant dissolution above its target pH." *Id.* at 9. Takeda asserts that it has shown as to Handa's formulation significant and rapid release of dexlansoprazole at target pH levels of 5.9 and 7.4, which falls within the scope of the '755 claims. *Id.*

Takeda also rejects Handa's contention that the applicants' reliance on the dissolution testing of Dr. Kurasawa during patent prosecution in the PTO contradicts Dr. Charman's position. *Id.* According to Takeda, Dr. Kurasawa's test was conducted at pH 6.8, a pH level "much lower than the pH 7.5 upper end of the pH range for the high-pH granule described in claim 1." *Id.* Thus, it contends, "[t]hat the granule released drug slowly at pH level of 6.8 does not indicate

how rapidly the drug would release within two hours at the higher pH of 7.5, and thus in no way undermines Dr. Charman's opinion." *Id.* Takeda also argues that the applicant's arguments distinguishing the Beckert prior art based on the Kurasawa tests are consistent with its position. *Id.* at 10. In particular, it argues:

> In its response to an Office Action rejecting the claims over a prior art reference by Beckert, Takeda distinguished the release profile for its Granule H from Beckert's Pellet B. Specifically, Takeda showed that Granule H achieved 30% dissolution after four hours, and nearly 100% after six hours, at pH 6.8, while Pellet B released not more than 20% after six hours at pH 6.8. See *id.* at DEX0007130; Charman Decl. ¶ 26. Under Handa's view of infringement, this minimal and slow release from the Beckert Pellet B would still have satisfied the claim limitations of the '755 patent; accordingly, Takeda's comparison would not have shown Beckert to be patentably distinguishable from the claimed formulations. The fact that the Examiner understood the different profiles of the two formulations, as shown by Takeda's comparative data, to be patentably distinct reflects his understanding that the amount and rate of release is necessarily critical to determining whether the limitations of the '755 patent are satisfied.

Id.

With respect to its arguments during claim construction, Takeda contends that it merely cited to Kurasawa to show that the term "begins to release" is not indefinite because a person skilled in the art would know how to perform dissolution testing like that performed by Kurasawa. *Id.* According to Takeda, it was not suggesting that the exact testing that was performed by Kurasawa should be used to assess infringement; indeed, the Kurasawa test fails to address "how the high-pH granule would behave at the upper end of the pH range, and thus offers incomplete information as to the high-pH-releasing granule limitation, and provides no information concerning the behavior of the low-pH granule in the claimed 5.0 to 6.0 pH range." *Id.* at 10-11.

[redacted]

c. Handa's Reply

In its reply brief, Handa contends that Takeda is improperly attempting to import additional limitations into the asserted claims. Handa Reply at 3. Handa reiterates its position that there is no support in the '755 Patent specification for Dr. Charman's position that release does not begin unless at least 10% of the dexlansoprazole is released over two hours. *Id.* at 5. Handa also rejects Takeda's reading of the prosecution history, contending that its "effort to distinguish the Kurasawa declaration in the file history is . . . weak and barely intelligible." *Id.* Handa contends that Takeda merely offers speculation that the release exhibited in the Kurasawa tests would have been more rapid at a higher pH level but that this is "irrelevant." *Id.* According to Handa, what matters is that both the patent specification and the Kurasawa declaration teach dissolution testing for "far more than the two-hour limit proposed by Takeda." *Id.* at 6.

Furthermore, Handa asserts, Takeda's new claim construction position is based almost entirely upon extrinsic evidence, which is disfavored in claim construction. *Id.* (citing *Vitronics Corp. v. Conceptronic*, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)). Rather, Handa contends, the Court should look to the ordinary meaning of the claim language as understood by a person of ordinary skill in the art, which in this case is so straightforward that it can be understood by a lay judge. *Id.* (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)). According to Handa, "a person having ordinary skill in the art would understand the term 'released' as used in the asserted claims of the '755 Patent to have its plain meaning in the context of in vitro testing—i.e., any release of drug from the dosage form into the dissolution medium." *Id.* n. 3 (citing Amiji Decl., Ex. 5, ¶ 41). Finally, Handa rejects Takeda's reliance on extrinsic evidence such as the USP and the FDA Guidelines on the grounds that these extrinsic documents are not referenced in the '755 Patent and there is no justification for turning to this extrinsic evidence to modify the meaning of the claims. *Id.* at 7.

d. Supplemental Briefs

Following the February 8 motion hearing, the parties in this case and the related cases submitted supplemental briefing at the request of the Court addressing whether it should engage in additional construction of the release term of the '755 Patent. *See* Case No. C-11-0840 JCS,

Docket Nos. 251 (Takeda), 252 (Handa); Case No. 11-1609, Docket No. 223 (TWi); Case No. C-11-1610, Docket No. 228 (Impax).

4. Infringement of the '276 Patent

a. Handa's Motion

Handa asserts that it is entitled to summary judgment of non-infringement of the '276 Patent because Takeda has not provided any evidence to show that: 1) the dexlansoprazole API used in the ANDA product [redacted] (as required by claims 2 and 3); or 2) the ANDA product is a pharmaceutical composition comprising [redacted] *Id.* at 10-11. According to Handa, it is undisputed that [redacted] and that neither Takeda nor its expert, Dr. Myerson, has offered any test results showing that the finished ANDA product contains [redacted] *Id.* at 11. This omission is particularly telling, Handa contends, because [redacted] Indeed, Handa points out, [redacted]

Handa also points to [redacted]

[redacted]

In addition, [redacted]

[redacted]

Handa contends that the basis for Takeda's claim that Handa's ANDA product infringes the '276 Patent is simply "[redacted]

According to Handa, [redacted]

[redacted]

Handa also addresses the specific documents upon which Dr. Myerson relies, arguing that none of them supports Dr. Myerson's position. *Id.* at 15-18. First, Handa rejects Dr. Myerson's reliance on [redacted]

Similarly, Handa contends that Dr. Myerson's reliance on [redacted]

[redacted]

Likewise, Handa rejects Dr. Myerson's reliance [redacted]

Handa also rejects Dr. Myerson's reliance on [redacted]

Finally, Handa rejects Dr. Myerson's reliance on [redacted]

b. Takeda's Opposition

Takeda argues that fact questions preclude entry of summary judgment of non-infringement of the '276 Patent. Opposition at 19. According to Takeda, it is undisputed that Handa's formulated product, which includes the active ingredient dexlansoprazole and the

[redacted] *Id.* This question is highly factual, Takeda contends, and will require the Court to evaluate the significance of [redacted] According to Takeda, these documents are sufficient to give rise to a fact question as to the existence of crystalline dexlansoprazole in the finished ANDA product.

c. Handa's Reply

Handa contends that Takeda has not established a genuine dispute of material fact as to the existence of [redacted] but rather relies "solely on uncorroborated speculation." Reply at 7-8.

III. ANALYSIS

A. Legal Standards

1. Legal Standard Governing Summary Judgment

Summary judgment on a claim or defense is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show the absence of a genuine issue of material fact with respect to an essential element of the non-moving party's claim, or to a defense on which the non-moving party will bear the burden of persuasion at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to designate "specific facts showing there is a genuine issue for trial." *Id.* "[T]he inquiry involved in a ruling on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof that would apply at the trial on the merits." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the non-movant. *Id.* at 255.

2. Legal Standard Governing Patent Infringement

A determination of infringement is a two-step process. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The first step is claim construction, which is a question of law to be determined by the court. *Id.* The second step is an analysis of infringement, in which it must be determined whether a particular device infringes a properly construed claim. *Id.* A device literally infringes if each of the limitations of the asserted claim is found in the accused device. *Id.* The patentee always bears the burden of proof on infringement. *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, a patentee is entitled to summary judgment if it can show that it is "more likely than not" that the accused product possesses all of the elements of the asserted claim. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (*citing Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986)). Once the patentee has made a prima facie showing that it is more likely than not that all the claim limitations are met, the accused infringer must come forward with more than a scintilla of evidence to create a genuine issue of material fact as to non-infringement to survive a patentee's summary judgment motion. *Id.* Conversely, an accused infringer is entitled to summary judgment of non-infringement where it shows "that the patentee failed to put forth evidence to support a finding that a limitation of the asserted claim was met by the structure in the accused devices." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1578 (Fed. Cir. 1989).

Takeda asserts its infringement claims under 35 U.S.C. § 271(e)(2); it also seeks a declaratory judgment of infringement and injunctive relief under 35 U.S.C. § 271(a) and the Declaratory Judgment Act. Section 271(e)(2) provides that:

> [i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United

States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

3. Legal Standard Governing Invalidity Based on Anticipation

Under 35 U.S.C. § 102(a), a patent may be anticipated if the claimed invention was described in a printed publication "before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). "To anticipate a patent claim under 35 U.S.C. § 102, 'a reference must describe . . . each and every claim limitation and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation.'" *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012) (quoting *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1341 (Fed.Cir.2011) (citation omitted)). The claim limitations may be disclosed "either expressly or inherently." *EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 Fed. Cir. 2001); *In re Kratz*, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound's existence was not known)). In *Continental Can Co. v. Monsanto Co.*, the Federal Circuit explained that "inherent" disclosure "may not be established by probabilities or possibilities" but must be "necessarily present in the thing described in the reference" as viewed by persons of ordinary skill in the art. 948 F.2d 1264, 1269 (Fed. Cir. 1991).

"[A]nticipation is a question of fact, including whether or not an element is inherent in the prior art." *Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). The accused infringer bears the burden of proving invalidity of the asserted patent by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 U.S. (2011). In *Microsoft*, the Court explained that this heavy burden is based on § 282(a) of the Patent Act, which provides that an issued patent "shall be presumed valid" and that "[t]he burden of establishing invalidity ... rest[s] on the party asserting such invalidity." Nonetheless, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 2003) (*Amgen II*), the

Federal Circuit announced an exception to this rule, holding that a presumption of enablement applies to both the claimed and unclaimed disclosures of prior art patents. *Amgen II*, 314 F.3d at 1355. Thus, the burden is on the *patentee* defending against an invalidity challenge based on a prior art patent to "present persuasive evidence of non-enablement to overcome this presumption." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1307 (2006) (*Amgen III*).

The Federal Circuit in *Amgen II* reasoned as follows:

> In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue. . . . *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (C.C.P.A.1980) ("[W]hen the PTO cited a disclosure which expressly anticipated the present invention ... the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior art patent] by a preponderance of the evidence." (citation omitted)). The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled. *Id.* We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff. Thus, a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled. Like the applicant in ex parte prosecution, however, the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art. If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.

Amgen II, 314 F.3d at 1355.

In a footnote, the Federal Circuit in *Amgen II* noted that "by logical extension, our reasoning here might also apply to prior art printed publications as well," *id.* n. 22, and recently, in *In re Antor Media Corp.*, the Federal Circuit squarely held "that a prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent

applicant or patentee." *Id.* at 1288. In *Antor*, the Federal Circuit rejected the patentee's argument, based on § 282, that the presumption should not extend to non-patent prior art, explaining that in *Amgen*, the court did not rely only on § 282 as the source of the presumption but also on that fact that it is "procedurally convenient to place the burden on the applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not enabling or operative." *Id.*

Although the Federal Circuit in *Antor* addressed whether the presumption of enablement applied in the context of patent prosecution, the reasoning of that decision persuades the Court that the presumption also applies in the district court, just as the Federal Circuit found in *Amgen II* with respect to patent prior art cited to establish anticipation. Therefore, the Court finds that where a prior art printed publication is asserted in support of an anticipation defense, the prior art is presumed enabled unless the patentee can present "evidence of nonenablement that a trial court finds persuasive." *See Amgen II*, 314 F.3d at 1355. Further, the Court concludes based on the *Amgen II* court's reliance on *In re Sasse* that the amount of evidence required to rebut the presumption is a preponderance of the evidence and that if the patentee meets that burden, the court must then exclude the prior art in its anticipation analysis. *See id*; *see also Amgen III*, 457 F.3d at 1307 (noting that on remand, the district court found that the patentee met its "burden of proving by a preponderance of the evidence" that the prior art that was alleged to anticipate was not enabled and affirming the district court's holding).

B. Subject Matter Jurisdiction over '282 Patent Infringement Claim under Hatch-Waxman Act

Handa contends that there is no subject matter jurisdiction over Takeda's '282 Patent infringement claim under 35 U.S.C. §271(e)(2) because Takeda did not list that patent in the Orange Book. The Court disagrees.

The Hatch-Waxman Act gives manufacturers of generic drugs a safe harbor in which to develop their products without threat of patent litigation. *See* 35 U.S.C. § 271(e)(1). In return, Congress gave patentees the right to challenge a generic drug when the generic manufacturer files an ANDA, deeming the filing of the ANDA "a defined act of infringement sufficient to create

case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). This compromise is embodied in subsections (1) and (2) of 35 U.S.C. § 271(e), which provides, in relevant part as follows:

> (e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.
>
> (2) It shall be an act of infringement to submit--
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,
>
> . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e) (1) & (2).

Further, "the Hatch-Waxman Act . . . establishes a procedure called a 'Paragraph IV certification,' 21 U.S.C. § 355(j)(2)(A)(vii)(IV), by which an entity that seeks to market a generic counterpart of a patented drug product or method of use, before the patent has expired, may challenge the patent before actually marketing the drug." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330 (Fed. Cir. 2013). As part of this procedure, most patentees and New Drug Applicant ("NDA") holders are required to list patents related to their approved drugs in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). 21 U.S.C. § 355(b)(1). A company that manufactures generic drugs, in turn, is required to consult the Orange Book before filing an ANDA and certify that either (I) no patent

information is listed in the Orange Book for the proposed generic drug; (II) that the listed patents have expired; (III) that the listed patents will expire before the generic company markets its product; or (IV) that the patents listed are invalid or will not be infringed by the generic drug (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

Here, Takeda has alleged jurisdiction under 28 U.S.C. § 1338, which provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." Thus, the existence of subject matter jurisdiction over Takeda's § 271(e)(2) claim based on the '282 Patent depends on whether that claim "arises under" the Hatch-Waxman Act even though Handa's ANDA did not include a Paragraph IV Certification. Some courts have found that a Paragraph IV Certification is a jurisdictional requirement for bringing a claim under the Hatch-Waxman Act. *See, e.g., Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007). In *Eisai*, the court recognized that "[t]he plain text of § 271(e)(2) does not require that the alleged infringer file an ANDA with a Paragraph IV certification, or that the drug claims be listed in the Orange Book." *See* 2007 WL 4556958, at *9. Nonetheless, based on extended discussion of the ANDA process in decisions by the Federal Circuit, the *Eisai* court concluded that a Paragraph IV requirement should be "read into" § 271(e)(2). *Id.* at * 12.

The undersigned does not find the reasoning of *Eisai* persuasive given the clear language of the statute and the fact that none of the Federal Circuit cases addressed in *Eisai* directly addressed the question of whether a Paragraph IV Certification was required in order for a patentee to bring an infringement claim under the Hatch-Waxman Act. *See id.* at *11 ("The Federal Circuit has never squarely faced the question before this Court"). The Federal Circuit subsequently resolved any doubt on this issue in *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012). In *AstraZeneca*, the Federal Circuit held that under the Hatch-Waxman Act, "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims." 669 F.3d at 1376-77.

Further, in *Caraco Pharm. Labs.., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), the Supreme Court also made clear that a Paragraph IV certification is not a jurisdictional requirement for bringing an action under the Hatch-Waxman Act. In that case, the generic drug manufacturer, Caraco, initially included a Paragraph IV certification in its ANDA but later inserted a statement under § 355(j)(2)(A)(viii) ("section viii statement"). 132 S. Ct. at 1679. A section viii statement asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents and is an alternative to a Paragraph IV certification for obtaining FDA approval. *Id.* at 1677-1678. Before the FDA had approved the generic on the basis of the section viii statement, however, the patentee, Novo, amended its use codes to cover the uses for which the generic manufacturer sought approval. *Id.* at 1679. In the ensuing Hatch-Waxman infringement action initiated by Novo, the generic manufacturer asserted a counterclaim seeking to compel Novo to amend its use codes such that Caraco would be able to obtain FDA approval under section viii rather than under Paragraph IV. The question before the Supreme Court was whether Caraco could assert such a counterclaim. In that context, Novo argued that there was no subject matter jurisdiction over the action. 132 S. Ct. 1670, 1680 n.5 (2012). The Court rejected that argument, reasoning as follows:

> On Novo's theory, [a section viii] statement (unlike a paragraph IV certification) does not count as an act of infringement under the patent statute, see 35 U.S.C. § 271(e)(2)(A), and so cannot provide a jurisdictional basis for the suit. But that argument is wrong even assuming (as Novo contends) that Caraco's section viii filing terminated its paragraph IV certification and that a section viii filing is not an act of infringement. The want of an infringing act is a merits problem, not a jurisdictional one. Nothing in the section of the statute defining certain filings as acts of infringement suggests anything to the contrary. And "we are not inclined to interpret statutes as creating a jurisdictional bar when they are not framed as such." *Stern v. Marshall*, 564 U.S. ——, ——, 131 S. Ct. 2594, 2607, 180 L.Ed.2d 475 (2011). In the absence of such a bar, the federal courts have jurisdiction over this suit for a single, simple reason: It "ar[ose] under a[n] Act of Congress relating to patents." 28 U.S.C. § 1338(a).

Id.

In light of the *Caraco* decision and the Federal Circuit's recent decision in *Astrazeneca*, this Court joins a number of other district courts in concluding that there is no requirement under the Hatch-Waxman Act that a patent must be listed in the Orange Book in order for a drug manufacturer to bring an infringement action based on that patent against an ANDA applicant. *See Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 2013 WL 591976 (D.N.J. Feb. 14, 2013) (declining to follow *Eisai* on the basis that "more recent precedent of the Federal Circuit controls" and holding that under *AstraZeneca* it is clear that the requirements for jurisdiction in the district courts are met once a patent owner alleges that the filing of an ANDA infringes its patent under § 271(e)(2), regardless of whether the ANDA includes a Paragraph IV certification); *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012) (rejecting the reasoning and "sweeping conclusion" of *Eisai* that the court lacked jurisdiction under the Hatch-Waxman Act where there was no Paragraph IV certification); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009) (holding that "[t]here is no requirement that infringement actions against ANDA filers must be based on patents listed in the Orange Book"); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004) ("The language of § 271(e)(2)(A) does not require that the ANDA contain a [Paragraph IV] certification to constitute an act of infringement. It only requires that the [ANDA] application be filed under § 355(j)"); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009) (holding in a case involving an Abbreviated New Animal Drug Application that "a Paragraph IV certification is not required to trigger an infringement action under § 271(e)(2)").

Therefore, the Court concludes that it has subject matter jurisdiction over Takeda's infringement claim under § 271(e)(2) even though the '282 Patent was not listed in the Orange Book.

C. Infringement of the '282 Patent

Takeda requests summary judgment of infringement of the '282 Patent on two theories. First, it seeks summary judgment on Count VII of the Second Amended Complaint, for infringement of claim 1 the '282 Patent under § 271(a), based on the undisputed fact that Handa

[redacted]

[redacted] Second, it contends that [redacted] and therefore infringes claims 1 and 2 of the '282 Patent under § 271(e)(2) and § 271(a) (Counts IV and VII).[12] For the reasons discussed below, the Court finds, as a matter of law, that the finished product contain the [redacted] and therefore, that Takeda is entitled to summary judgment of infringement on Count IV of its complaint, asserted under the Hatch-Waxman Act. The Court also finds, as a matter of law, that the API used in Handa's ANDA product [redacted] The Court declines to enter summary judgment in Takeda's favor on Count VII, however, because Takeda has not established that it meets the constitutional requirements for bringing claims under the Declaratory Judgment Act.

To establish a case or controversy under Article III of the U.S. Constitution, a claim must be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)(quotations omitted). Some courts have permitted claims seeking declaratory judgment of infringement under § 271(a) based on the filing of an ANDA. *See, e.g., Cephalon v. Sandoz,* Inc., 2012 WL 682045 , at *5 (D. Del. Mar. 1, 2012); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.,* 2009 WL 6337911, at *13-14 (E.D. Wis. Sept. 24, 2009) . Other courts, however, have held that such claims are not sufficiently real and immediate to satisfy the requirements of *MedImmune*. *See, e.g., Eisai*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Las. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 983 (N.D. Ill. 1995) (questioning whether such a claim is consistent with Congress' intent in providing a safe haven for generic manufacturers under the Hatch-Waxman

[12] As noted above, claim 2 depends from claim 1 and adds a limitation requiring a "pharmaceutical composition comprising the amorphous compound according to claim 1 and a pharmaceutically acceptable excipient, carrier or diluent." Handa does not dispute that this [redacted] conversely, Takeda does not contend that [redacted] and therefore asserts its claim under § 271(a) only as to claim 1 of the '282 Patent.

Act). As the parties have not briefed this issue, the Court does not reach the question of whether Takeda can establish the existence of a "definite and concrete" controversy on its infringement claims under § 271(a) and the Declaratory Judgment Act.

1. Use of [redacted]

It is undisputed that an [redacted] is used in the manufacture of Handa's ANDA product. The Court also rejects Handa's contention that Takeda has not asserted a claim under § 271(a) on this basis.

Count VII seeks declaratory judgment of infringement as to all of the Asserted Patents, including the '282 Patent, under § 271(a). Further, Count VII alleges that: 1) "Defendants' commercial *manufacture*, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules will constitute infringement of . . . the '282 . . .Patent[];" 2) "Defendants' infringing commercial *manufacture*, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules complained of herein will begin following FDA approval of ANDA No. 202-24;" and 3) Plaintiffs thus are entitled to a declaration that the *making*, using, sale, offer for sale, and importation into the United States of the Proposed Capsules according to ANDA No. 202-294 infringe one or more claims of the Asserted Patents." SAC, ¶¶ 61-63 (emphasis added). These allegations are sufficient to encompass both of Takeda's theories of infringement, that is, that Handa infringes both on the basis of [redacted] Therefore, if Takeda can establish at trial that it has standing under the Declaratory Judgment Act, and that such use is not protected under the safe harbor provisions of the Hatch-Waxman Act, it will be entitled to judgment in its favor on Count VII to the extent that claim is based on use of the API used in Handa's ANDA product.

2. [redacted]

Takeda also seeks summary judgment of infringement of claims 1 and 2 of the '282 Patent based on what it contends is substantial evidence that the formulated ANDA product contains an [redacted] As noted above, the Court has construed the term "amorphous compound" to require a compound that is solid and non-crystalline. The undisputed

evidence is that [redacted] *See* Myerson Decl., Ex. 11 at HANDEX0021652, HANDEX0021657. Thus, aside from the question of whether Takeda can establish standing with respect to its claim under the Declaratory Judgment Act, discussed above, the only remaining question is whether the [redacted] If so, Takeda is entitled to summary judgment of infringement under § 271(e).

The primary evidence offered by Takeda to establish that the dexlansoprazole used in Handa's drug product is [redacted] Such evidence may be used to establish infringement. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (citing *Forest Labs. v. Abbott Labs.*, 239 F.3d 1305, 1312 (Fed. Cir. 2001), *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006))("A patentee may prove infringement by 'any method of analysis that is probative of the fact of infringement' . . . , and circumstantial evidence may be sufficient"). Handa has pointed to no authority (nor has the Court found any) requiring that infringement must be established on the basis of testing of the ANDA product. To the contrary, at least with respect to statements made in the ANDA, the Federal Circuit has held that descriptions of the proposed generic drug "that directly address[ ] the issue of infringement will control the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). This rule is based on the strict statutory provisions requiring that generic drug manufactures "sell only those products that comport with the ANDA's description of the drug." *Id.* Further, "[t]here is no prohibition against using the admissions of a party, whether in the form of marketing materials or otherwise, as evidence in an infringement action." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1351 (Fed. Cir. 2007).

The Court finds that Handa made [redacted]

[redacted]

Although Handa contends that Takeda "overreaches" in its interpretation of these statements, [redacted] the Court finds that no reasonable jury could adopt such an interpretation of Handa's statements [redacted] In particular, in discovery and in support of its own request for summary judgment of non-infringement of the '276 Patent, Handa has taken the consistent position its ANDA product [redacted] Handa SJ Motion at p. v; *see also id.* at 1 ("[T]he ANDA Product [redacted] Takahashi Decl., Ex. 4 (Handa's First Supplemental Responses to Plaintiffs' First Set of Joint Interrogatories, June 15, 2012), at 10 (stating that Handa's "[redacted] Indeed, in its Reply

brief, Handa calls the evidence cited by Takeda to establish the existence of [redacted] "uncorroborated speculation." Reply at 8. As Handa has not pointed to any evidence that a s[redacted] Handa's representations that the [redacted] Further, given that these statements directly address the key issue upon which infringement of the '282 Patent by the ANDA product turns, the Court considers them to be binding judicial admissions. These admissions, as well as the statements Handa has made to the FDA, constitute substantial evidence of infringement by Handa's ANDA product of the '282 Patent.

The Court further finds that Handa has not identified specific facts, in the face of Takeda's prima facie showing of infringement, to establish the existence of a genuine issue of material fact. Handa points to Dr. Myerson's testimony, based on the [redacted] Handa on the ANDA product, that the [redacted] arguing that this creates a factual dispute. *See* Jansen Opposition Decl., Ex. 3 (Oct. 26, 2012 Myerson Dep. Tr.) at 112. Dr. Myerson, however, only testified that [redacted] *Id.* This testimony is not sufficient to establish a material issue of fact where Handa has consistently rejected the possibility that the [redacted] both in its statements to the FDA and in this litigation.

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[13] As Takeda points out in its Reply brief, the evidence presented at claim construction was consistent in treating solids as being either crystalline or amorphous and the Court treated them as such in its Claim Construction Order. *See* Takeda Reply at 6 ("it is a binary choice") (citing Decl. of Allan S. Myerson, Ph.D., in Support of Takeda's Opening Claim Construction Br. ("Myerson Claim Constr. Decl.") [D.N. 62] ¶ 81 ("Solids can be crystalline or amorphous."); *id* ¶ 23 ("Solids that are not crystalline and have no long range order . . . are said to be amorphous."); Myerson Rep. ¶ 22 (same); Claim Construction Opinion [D.N. 106] at 36 (noting references that show that an "'amorphous compound' lacks [] long range order")).

Accordingly, the Court finds that Takeda is entitled to summary judgment in its favor on Count IV, under the Hatch-Waxman Act, to the extent that claim is based on infringement of claims 1 and 2 the '282 Patent by Handa's ANDA product. To the extent that Takeda also asserts a claim of infringement under § 271(a) and the Declaratory Judgment Act based on the finished product, in Count VII, it will be entitled to judgment in its favor if it can establish at trial that it has standing under the Declaratory Judgment Act and that Handa's use of [redacted] is not protect by the safe haven provisions of the Hatch-Waxman Act.

D. Validity of the '282 Patent

Handa argues that the asserted claims of the '282 Patent are anticipated by the Larsson and Barberich references. This dispute turns primarily on two questions: 1) whether Larsson inherently discloses a solid amorphous compound of dexlansoprazole, as is required under claim 1 of the '282 Patent; and 2) whether the disclosure of amorphous dexlansoprazole in Barberich is enabled. The Court finds, as a matter of law, that Larsson does not inherently disclose an amorphous form of dexlansoprazole that meets this claim limitation. The Court further finds there is a fact question as to whether the disclosure in Barberich is enabled.

Inherent disclosure may not be established by "probabilities or possibilities." *Bettcher Industries, Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)). "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* For example, in *GlaxoInc. v. Novapharm Ltd.*, the defendant argued that the asserted patent was anticipated based on inherent disclosure in the prior art, citing evidence that its expert had reproduced the prior art method thirteen times, each time obtaining the claimed crystals. 52 F.3d 1043, 1047 (Fed. Cir. 1995). However, the patentee had presented evidence that two of its own experts had used the same method to produce different crystals. *Id.* Because the method described in the prior art did not "always yield" the claimed invention but rather, "*could* yield" something different, the Federal Circuit affirmed the district court's holding that there was no inherent disclosure and therefore, that the asserted patent was not anticipated.

Here, Handa's own evidence establishes that Larsson does not inherently disclose the "amorphous compound" limitation of the '282 Patent. In particular, when the UW researchers

attempted to follow strictly the protocol in Example 22, they first obtained a solid of racemic lansoprazole rather than an amorphous compound of dexlansoprazole. In other words, the UW research results show, at best, that following the method described in Example 22 *could* yield an amorphous compound of dexlansoprazole, not that it always or necessarily yields such a result. Further, the undisputed evidence shows that the UW researchers had to add a step to the process described in Example 22 by slowly adding an oxidizing agent to obtain the claimed compound. This evidence supports the conclusion that merely following the protocol that is actually described in Example 22 does *not* always yield the claimed compound. Thus, Handa's own evidence establishes, as a matter of law, that Larsson does not inherently disclose the amorphous compound of dexlansoprazole claimed in the '282 Patent.

Handa attempts to avoid this conclusion by relying on what it contends is evidence of agreement by all of the experts that repetition of the process in Example 22 will eventually result in the synthesis of the claimed compound. *See, e.g.,* Handa Reply at 12 n. 9 ("Takeda's reliance on *Bettcher* and *In re Oelrich* (Opp. at 16) is . . . misplaced, as agreement by experts on both sides on the result hardly constitutes the mere 'probabilities or possibilities' that were at issue in those cases"); *id.* at 14 n. 13 ("*Glaxo* and *Continental Can*, on which Takeda relies, are . . .both inapplicable as Takeda has introduced no evidence to contradict the experts' unanimous opinion that performing Example 22 will result in an amorphous solid"). Handa's repeated assertions of unanimity are not supported by the record, however. Dr. Myerson merely states that if you were to repeat the process in Example 22, "you should be *able*" to make an amorphous compound of dexlansoprazole but that it would be "very hard to do" and would be likely to take "a really long time." This testimony does not state that simply by following the procedure in Example 22 one would *necessarily* obtain the claimed compound. To the contrary, Dr. Myerson's testimony only supports the conclusion that one *could* obtain such a result – which the Federal Circuit has repeatedly held is not sufficient to establish inherency. Further, to the extent Dr. Myerson testifies that it would be "very hard to do," his testimony supports the conclusion that repetition of the process described in Example 22 would *not* always yield the claimed compound.[14]

[14] The Court assumes that Dr. Myerson's testimony is admissible without reaching that question.

Nor does Dr. Atwood's testimony support Handa's position. Dr. Atwood, like Dr. Myerson, merely testified that it was "possible" for the oil described in Larsson to become a solid through repetition of the Example 22 procedure, not that it necessarily would yield such a compound. More importantly, Dr. Atwood opined in his report that the Larsson prior art does not disclose the claimed compound, and addressed in detail the reasons for this opinion. *See* Jansen Decl., Ex. 11 (Atwood Report) ¶¶ 78-90. Therefore, the Court concludes that the testimony of the experts cited by Handa does not establish inherent disclosure; nor does the dispute between the parties' experts give rise to a genuine dispute of material of fact where Handa's own evidence establishes that the standard for inherent disclosure is not met as to the Larsson prior art.

Having found that Larsson does not inherently disclose the "amorphous compound" limitation of the '282 Patent, the remaining question is whether the Barberich references anticipate the asserted claims of the '282 Patent. The Barberich references, unlike Larsson, expressly disclose a solid amorphous compound of dexlansoprazole. *See* Rogers Decl., Ex. 10 (Barberich I) at IPXL-0009198 ("Compressed tablets may be prepared by compressing in a suitable machine the active ingredient in a free-flowing form such as powder or granules"). Thus, the question of whether Barberich anticipates turns on enablement. As discussed above, although it is Handa's burden to establish invalidity by clear and convincing evidence, the Federal Circuit has created an exception where the patentee seeks to defeat an invalidity defense on the basis that the prior art reference is not enabled. On that question, Takeda bears the burden of establishing lack of enablement by the preponderance of the evidence.

The test for enablement is whether a person "skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (citation omitted). In determining whether a disclosure requires undue experimentation, courts may consider the following factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

ALZA Corp. v. Andrx Pharmaceuticals, LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). Although Barberich doesn't offer guidance as to how to create an amorphous compound of dexlansoprazole, it references Larsson. As discussed above, the UW Report indicates that at least *some* experimentation was required to obtain the claimed amorphous compound of dexlansoprazole using the disclosure of Example 22 in Larsson. On the basis of that evidence, the Court cannot find as a matter of law that Takeda will be unable to meet its burden at trial of showing that Barberich is not enabled on the basis of its incorporation of Larsson. Therefore, the Court finds that there is a fact question as to whether the Barberich disclosure of amorphous dexlansoprazole is enabled. The Court denies Handa's request for summary judgment of anticipation as to the '282 Patent.

E. Infringement of the '276 Patent

Handa contends that it is entitled to summary judgment of non-infringement of the '276 Patent because Takeda has not shown that there is a genuine dispute of material fact that the ANDA product [redacted] Handa argues that Takeda has not established a factual dispute because [redacted] Dr. Myerson, however, has opined that [redacted] Myerson Report ¶ 64. This evidence is sufficient to establish a factual dispute.

Handa's reliance on Dr. Myerson's [redacted] in support of his infringement opinion is misplaced. [redacted] Nor is the Court persuaded that the [redacted] are sufficient to establish non-infringement of the '276 Patent as a matter of law. While Takeda concedes that the [redacted]

[redacted] More significantly, the claims cover *any* crystalline form of dexlansoprazole. [redacted]

The Court finds that a genuine issue of material fact exists as to whether Handa's ANDA product contains [redacted] Accordingly, entry of summary judgment of non-infringement of the '276 Patent is not appropriate.

F. Infringement of the '755 Patent

Handa requests summary judgment of non-infringement of the '755 Patent based on the [redacted] Because the Court finds that Takeda's position on this issue amounts to a request for a revised construction of the release term, the Court first addresses whether such a revision is appropriate.[15] Having carefully considered the supplemental claim construction briefs and supporting materials filed by the parties in this action and the related actions, the Court declines to revise its previous construction. Further, the Court finds that under that construction, the undisputed facts establish, as a matter of law, that Handa's ANDA product does not infringe the asserted claims of the '755 Patent.

As noted above, at the claim construction stage of the case, the Court construed the phrase "released in the pH range of no less than 5.0 to no more than 6.0" to mean "begins to be released from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0." The Court's construction makes clear that the range set forth in the release term is a threshold at which release begins. The Court acknowledged in its claim construction order that the parties disagree about what testing should be conducted to determine infringement but found that this disagreement goes to infringement rather than indefiniteness, rejecting the defendants' argument that a person skilled in the art would not know how to determine when release "begins." Now, however, Takeda argues that there is a fact question on infringement -- even though the

[15] The general legal standards governing claim construction are set forth in the Court's claim construction order. Therefore, the Court does not repeat them here.

undisputed evidence (Takeda's own testing) shows [redacted] according to Takeda's expert, such release does not occur unless at least 10% of the drug is released in a 2-hour period. Takeda is essentially asking the Court to adopt a broader construction of the release term than it adopted in its claim construction order. In light of the intrinsic evidence, the Court concludes that Takeda's position is incorrect.

First, the Court looks to the claim language. "Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning." *Elekta Instrument S.A. v. O.U.R. Scientific International, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (citation omitted). The plain language of the release term of claim 1 sets forth a specific range of pH values in which release of the API must begin. This range captures the idea set forth in the specification that composition (ii) dissolves at a pH of "about 5.5." *See* '755 Patent, col. 2, ll. 48-53 (stating in the "Disclosure of Invention" section that the invention provides a "capsule . . . which comprises a tablet, granule or fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5"). In other words, the claim language *already* allows for some dissolution to occur below the 5.5 target pH level for composition (ii) while remaining within the scope of the claim. Were the Court to insert further qualifying language in its construction that allowed release *below* the lower end of the range claimed by the inventors, it would not only be ignoring the ordinary meaning of the claim term but would also be rendering the lower end of the range in the claim superfluous to the extent that release would be permitted both below 5.0 *and* above 5.0. *See Elekta*, 214 F.3d at 1307 (reversing district court's construction of the term "only within a zone extending between latitudes 30° - 45°" as meaning "beginning at the edge of the helmet (0°) and extending to a point between 30° - 45°" on the basis that it was inconsistent with ordinary meaning of claim language and rendered lower end of the range superfluous); *U.S. Philips Corp. v. Isasaki Elec. Co.*, 505 F.3d 1371, 1376 (Fed. Cir. 2007) (affirming district court's construction of term "between 10^{-6} and 10^{-4} <<mu>>mol/mm ^{3}" as meaning "between 1 x 10^{-6} and 1 x 10^{-44} <<mu>>mol/mm ^{3}" and noting that district court was correct that "the overall phrase - 'a quantity between -- and --' - is a construction that 'implies a specific range . . . it does not imply a range between two values which

are themselves ranges"). Thus, the unambiguous language of the claim supports a construction that does not permit release of the API outside of the claimed range.

Further, nothing in prosecution history or the specification of the '755 Patent persuades the Court that it is appropriate to read into the release term a requirement that release must be significant and rapid (or to state it somewhat differently, that the claim covers embodiments in which there is no *significant* release below the lower end of the range, pH 5.0). The parties hotly dispute the significance of: 1) the applicants' reliance on the Kurasawa testing during patent prosecution; and 2) the disclosure in columns 9 and 10 of the '755 Patent. Beyond the fact that both describe testing that was conducted over a longer period of time than Takeda asserts is appropriate for determining whether the release limitation is satisfied, suggesting that the two-hour limitation proposed by Takeda is incorrect, the Court finds that neither the prosecution history nor the passage in the specification offers significant guidance as to the construction of the release term.

On one hand, the Kurasawa testing revealed a dissolution rate of less than 5% dissolution after 2 hours and thus, the embodiment of the invention tested by Kurasawa would not have satisfied the "significant and rapid" requirement that Takeda asks the Court to read into the release term.[16] On the other hand, the single example describing testing in the specification, found in columns 9 and 10, arguably supports Takeda's position that claim 1 allows some release below the claimed pH ranges. That passage states as follows:

> It is desirable that the coating material is used alone or, if necessary, in combination so that the polymer is dissolved, preferably at a pH of 6.0 or above, more preferably at a pH of 6.5 or above, and further more preferably at a pH of 6.75 or above. . . . The rate of elution of active ingredient from the active-ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8.

[16]The Court notes that the Kurasawa testing involved the high pH granule rather than the low pH granule that is the subject of the release term. Nonetheless, at claim construction Takeda argued that the Kurasawa testing would have offered guidance to a person of ordinary skill in the art as to how to measure whether the release term was satisfied.

'755 Patent, col. 9, l. 65 - col. 10, l. 17. Neither of the examples, however, addresses whether (or when) the release described in them falls within the range set forth in the release term. Moreover, even if Takeda is correct that the passage in the specification describes an embodiment that is excluded under the Court's current construction of the release term, this does not justify modifying the construction as "the unambiguous language of the . . . claim controls over any contradictory language in the written description." *Elekta*, 214 F.3d at 1308. Finally, to the extent that the Court finds that the claims themselves are unambiguous, reliance on extrinsic evidence, such as the USP, is not a proper basis for varying the meaning of the term. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

For these reasons, the Court concludes that it is not appropriate to revise its construction of the release term to insert qualifying language requiring that release must be rapid and significant. Rather, the Court finds that a product falls outside of the ambit of claim 1 if there is any measurable release of the API from the low pH granule below the range specified in the release term. [redacted] the Court finds as a matter of law that that product does not infringe the asserted claims of the '755 Patent.

IV. CONCLUSION

For the reasons stated above, Takeda's motion is GRANTED. Handa's motion is GRANTED in part and DENIED in part.

IT IS SO ORDERED

Dated: April 8, 2013

Joseph C. Spero
United States Magistrate Judge

United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

FOR THE

NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD ET AL et al,

Plaintiff,

v.

HANDA PHARMACEUTICALS, LLC et al,

Defendant.

/

Case Number: CV11-00840 JCS

SEALED CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that I am an employee in the Office of the Clerk, U.S. District Court, Northern District of California.

That on April 8, 2013, I SERVED a true and correct copy(ies) of the attached, by placing said copy(ies) in a postage paid envelope addressed to the person(s) hereinafter listed, by depositing said envelope in the U.S. Mail, or by placing said copy(ies) into an inter-office delivery receptacle located in the Clerk's office.

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